



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,204	02/16/2004	Itzhak Bentwich	050992.0201.03USCP	2203
37808	7590	01/26/2010		
ROSETTA-GENOMICS c/o POLSINELLI SHUGHART PC 700 W. 47TH STREET SUITE 1000 KANSAS CITY, MO 64112			EXAMINER WOLLENBERGER, LOUIS V	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 01/26/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/708,204	Applicant(s) BENTWICH, ITZHAK	
	Examiner Louis Wollenberger	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31, 32 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31 and 39 is/are allowed.
- 6) ☒ Claim(s) 32 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 11/23/2009 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 8/21/2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Also acknowledged are applicant's amendments to the claims filed 11/23/2009. With entry of the amendment, claims 31, 32, and 39-42 are pending and under examination.

Priority

An earlier Action acknowledged Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c), and 35 U.S.C. 119(a)-(d).

It was stated Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(a)-(d), 119(e), and 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

It was stated the disclosures of prior-filed Application Nos. 60/468,251, 10/649,653, 10/651,227, 10/707,147 11/24/2003, 10/604,985, 10/604,926, 10/604,727, 10/604,726,

10/707,975, 10/707,980, and PCT/IL03/00998 fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for the instant claims drawn to SEQ ID NO:6527 and 15. That is, written description support for SEQ ID NO:6527 and 15 is not readily found in any of the prior filed applications to which priority is now claimed.

In a previous reply, Applicant stated and the Examiner noted instant SEQ ID NO:15 and 6527 are identical to SEQ ID NO:303 and 169, respectively, in Application No. 10/707,147, filed 11/24/2003. In view of Applicant's Remarks, for purposes of this examination the earliest effective filing date of the instant claims continues to be that of 10/707147: 11/24/2003.

The lack of priority finding is maintained, however, with regard each of the other prior-filed applications to which priority is claimed.

Specification

In the previous Action it was stated the application contains disclosure entirely outside the bounds of the allowed claims. Applicant was required to modify the brief summary of the invention and restrict the descriptive matter so as to be in harmony with the claims (MPEP § 1302.01).

In the reply filed 11/23/2009, Applicant has amended the specification to comply with the requirement. The amendment to the specification has been entered into the application. The objection to the specification is hereby withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41 and 42 each recite the limitation "the vector" in line 2 of each claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102—maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32, 40, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Tuschl et al. (WO 03/029459) "MicroRNA molecules."

Tuschl et al. disclosed the 22-nucleotide sequence of the mature mouse miR-151 (see Table 3, page 33; reproduced in part below). The sequence is 90% identical to instant SEQ ID NO:15, also 22-nucleotides in length, differing by only two nucleotides (underlined) from the mouse miR-151 disclosed by Tuschl et al.

20	miR-151	CUAGACUGAGGCUCCUUGAGGU
		{SEQ ID NO:179}

Instant SEQ ID NO:15: cuagacugaagcuccuugagga

Tuschl et al. taught that mature miRNAs have a length of 19-24 nucleotides, but in particular are 21, 22, or 23 nucleotides long (pg. 3). Tuschl et al. further taught and claimed any nucleotide sequence identical or complementary to any of the sequences disclosed in Table 3, which Table includes the mouse miR-151 sequence, SEQ ID NO:179. Tuschl et al. state their invention includes any sequence at least 80%, 90%, 95%, or 99% identical to the disclosed miRNA, SEQ ID NO:179, or its complement (pages 2 and 43). The sequences may be RNA or DNA (page 3). Accordingly, Tuschl et al. expressly contemplated (and therefore disclosed) every 22-nucleotide nucleic acid sequence that is 90% identical and complementary to the miR-151 disclosed therein at Table 3, shown above, including every DNA sequence encoding each possible 22-nucleotide sequence in this genus (see page 2 for example). This disclosed list of sequences necessarily includes the instantly claimed SEQ ID NO:15 and its complement. At pages 4-5, Tuschl et al. taught vectors comprising these sequences. At page 21 it is taught that miRNAs are highly conserved and that almost every miRNA cloned from mouse was also encoded in the human genome. Tuschl et al. expressly recommend cloning, sequencing, and detecting miRNAs in vertebrate and invertebrates using known techniques and those disclosed therein to investigate miRNA function.

In view of this disclosure, one of skill would instantly recognize each 22-nucleotide sequence 80% and 90% identical and complementary to the mouse miR-151 shown in Table 3 as fully as if each sequence was written out. This list of sequences necessarily includes instant SEQ ID NO:15 and its complements as well as DNA sequences encoding SEQ ID NO:15. These sequences are also indistinguishable from the instantly claimed probes.

Thus, Tuschl et al. anticipates the claimed nucleic acids.

Response to Arguments

Applicant's arguments filed 11/23/2009, traversing the instant rejection over Tuschl et al. (WO 03/029459) have been fully considered but are not persuasive.

A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named (MPEP 2131.02, citing *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990).

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

In the instant case, Tuschl et al. expressly described a nucleotide sequence having an identity of at least 90% to any sequence shown in Table 3 therein (see claims and page 2). Table 3 lists SEQ ID NO:179, a 22-nucleotide sequence that is 90% identical to instant SEQ ID NO:15 (having 20 of 22 nucleotides in common). Given that the RNA bases at each position can only be U, C, G, or A, one of skill would instantly have envisioned every 22-nucleotide sequence that is at least 90% identical to (i.e., that has at least 20 bases in common with) SEQ ID NO:179. There is no ambiguity with regard to the complete 22-nucleotide sequence or need to consider any other variable in order for one to envision each sequence expressly disclosed by Tuschl et al.—the substituents at each position are sufficiently limited and well delineated. One of skill would have been able to write each sequence in the list of sequence 90% identical to SEQ ID NO:179.

Therefore, Tuschl et al. had described each of these 22-nucleotide sequences as fully as if they had written each sequence. There is no need to write out each sequence, since the express description in Tuschl et al. concisely discloses each sequence contemplated by Tuschl et al. for inclusion in their invention.

Applicant states a genus does not anticipate a species within the genus, and cites *Bristol-Myers Squibb Co. v. Ben Venue Laboratories Inc.* However, this case is not precedential and the facts therein are not analogous to those of the instant application. Here, there is no vague allegation that one of skill would recognize the claimed sequence based on general knowledge in the prior art. Instead, the rejection relies on a single reference, Tuschl et al., which expressly taught that their invention included every sequence that is at least 90% identical to the disclosed 22-mer, SEQ ID NO:179. One of skill would have envisioned each 22-nucleotide sequence on that list without having to consult any other reference.

Applicant supplies a calculation of the number of possible sequences disclosed by Tuschl et al., and states there are over 7500 "choices." However, this argument only substantiates the rejection, showing that, indeed, the list is necessarily finite and defined, otherwise how could one even presume to enumerate the number of sequences. Moreover, the idea of "choices" is not germane to anticipation. There is no need to show one of skill would have had to pick or choose from the list, but simply that one of skill could have envisioned each sequence on the list, and that the list necessarily includes the sequence now claimed. Applicant does not dispute the fact that the list of sequences includes any of those claimed by applicant. Further, Applicant provides no evidence to show one of skill could not have envisioned each sequence on the list disclosed by Tuschl et al. based on the express language therein, succinctly describing each sequence.

Furthermore, the instant claims require no function. The claims are drawn simply to an isolated nucleic acid selected from the group consisting of SEQ ID NO:15, the DNA encoding SEQ ID NO:15, and any complements thereto. Tuschl et al. disclosed all such sequences.

Finally, it is noted that previously Applicant himself had claimed a genus of sequences “at least 80% identical to SEQ ID NO:15 and 6527” even though the instant application as filed does not, in fact, list or expressly write out each such sequence. See claims filed 2/16/2004 and 11/22/2006. Presumably the position of applicant at the time such claims were presented was that all such sequences were adequately described by their specification in the manner required by 35 USC 112, first paragraph. In this regard, the disclosure of Tuschl et al. is commensurate with Applicant's, and is no less descriptive. Indeed, in WO/03/029459, Tuschl et al., like Applicant, also claimed all sequences at least 80% identical to any of those shown in Table 3 therein.

Accordingly, the rejection of the claims as being anticipated by Tuschl et al. is maintained.

Claim Rejections - 35 USC § 102—withdrawn

The rejection of Claims 39-42 under 35 U.S.C. 102(e) as being anticipated by Venter et al. (US Patent 6,812,339) is withdrawn in view of the amendments to the claims filed 11/23/2009.

The rejection of Claims 40 and 42 under 35 U.S.C. 102(b) as being anticipated by Zhao et al. (1997) GenBank Acc. No. AQ420078, first seen at NCBI on Mar 23 1999 12:30 AM is withdrawn in view of the amendments to the claims filed 11/23/2009.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore can be reached on (571)272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Primary Examiner, Art Unit 1635
January 19, 2010